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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/679,950

10/06/2003

Marcel Hunn

33635/US

3584

74307

7590

07/14/2008

Dorsey & Whitney LLP  
IP Department, ATTN: Disetronic Licensing AG  
50 South Sixth Street, Suite 1500  
Minneapolis, MN 55402-1498

EXAMINER

MACNEILL, ELIZABETH

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

07/14/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/679,950	<b>Applicant(s)</b> HUNN ET AL.	
	<b>Examiner</b> ELIZABETH R. MACNEILL	<b>Art Unit</b> 3767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3.5,8,10,11,13,14,19-21,33,37,54 and 56-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3.5,8,10,11,13,14,19-21,33,37,54 and 56-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/9/08</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 3, 5,8,10,13,14,19, 21 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Bley et al (US 5,762,630).

Bley teaches a cannula (117 and 113) composed a first material (shape memory polymer such as MM-3510, Col 4 at line 50) which is thermally susceptible, and a second material (hub 117).

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 20, 33, 37, and 56-60 rejected under 35 U.S.C. 103(a) as being unpatentable over Comaish (GB 2,282,760, cited by applicants 1/17/06) in view of Jiang (US 5,349,045).

Comaish teaches a cannula with outer layer (2) and inner layer/removable tube (4) where the outer layer degrades after implantation in the body. The outer layer may puncture the body (with sharpened tip 3). See abstract. Comaish teaches

various materials for the construction of his device (page 4) but not a water-absorbing polyamide.

Jiang teaches that a water absorbing polyamide may be used for medical devices, includes devices with puncture the skin (staples, clip) or drug delivery devices (cannulae, tubes). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the water-absorbing polyamide of Jiang with the catheter of Comaish as a simple substitution of one material for another which acts in the same way (by degrading in the body).

2. Claims 5, 8, 10, 11, 13, 20, 21, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Comaish (GB 2,282,760, cited by applicants 1/17/06) in view of Bley

Comaish teaches a cannula with outer layer (2) and inner layer/removable tube (4) where the outer layer degrades after implantation in the body. The outer layer may puncture the body (with sharpened tip 3). See abstract. Comaish teaches various materials for the construction of his device (page 4) but not a thermally degrading polymer.

Bley teaches a thermally degrading polymer cannula (see above). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the thermally degrading material of Bley with the catheter of Comaish as a simple substitution of one material for another which acts in the same way (by degrading in the body).

### ***Response to Arguments***

2. Applicant's arguments filed 11 June 2008 have been fully considered but they are not persuasive. Regarding Bley, applicant argues that the distal taper creates a flow build-up at the distal end. This is only true if the lumen of the catheter also tapers, not just the wall. There is nothing to suggest that the lumen of the catheter tapers in the disclosure and in most catheters only the outer wall has a distal taper, not the lumen. Next applicant argues that Bley is not capable of piercing the body/septum. Bley's stylet 113 has a Shore D hardness of 78 (Fig 2). This hardness is capable of piercing the human body and/or a septum (see Lambert US 5,250,066 at claim 4). Bley's stylet is also stiff enough to move past an internal valve in the introducer which may be similar to a septum (Col 4 line 38).

### ***Conclusion***

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/  
Examiner, Art Unit 3767  
/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767

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